APR 10 2014

510(k) Summary
(K132825)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___04/08/2014___

1. Submission Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	RetroMTA-OrthoMTA II
Common Name:	Root Filling Material
Classification Name:	Root Canal Filling Resin
Classification:	Class II, 21 CFR 872.3820
Classification Product Code:	KIF

4. Predicate Device:

OrthoMTA(K102575) by BioMTA

5. Device Description:

The major compositions of the RetroMTA-OrthoMTA II are dicalcium silicate, tricalcium silicate and tricalcium aluminate, and it has been showing good sealing ability and biocompatibility. It is prepared as a mixture of powder and water and is used in a putty form which gradually hardens in the oral environment. RetroMTA-OrthoMTA II is ideal for orthograde root canal filling. It is compositionally formulated to have the physical properties, setting requirements and characteristics necessary for a clinically effective root canal filling material.

6. Intended Use:

The RetroMTA-OrthoMTA II is indicated for use as:

- Orthograde root canal filling material
- Repair of root perforations during root canal therapy(endodontic therapy), or as a consequence of internal and external resorption.
- Repair of root canals as an apical plug during apexification
- Root end filling
- Pulp capping

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results met the preset test criteria.

- ISO 6876 - Setting time, Solubility and Radiopacity
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Oral Mucous Irritation & Sensitization
- ISO 10993-11 - Acute systemic toxicity
- Other bench testing - Appearance, weight, and package integrity

8. Substantial Equivalence

The RetroMTA-OrthoMTA II is substantially equivalent to the OrthoMTA(Mineral Trioxide Aggregate) (K102575) manufactured by BioMTA. The difference between RetroMTA-OrthoMTA II and the predicate device is that the RetroMTA-OrthoMTA II uses zirconium oxide replacing bismuth oxide which was used in the predicate device. The use of zirconium oxide allows shorter setting time.
The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that RetroMTA-OrthoMTA II is safe, effective and substantially equivalent to the predicate device.

The table on the following page summarizes technological characteristics of the subject device as compared to the predicate.

Properties	Subject Device	Predicate Device
510(k) Number	K132825	K102575
Device Name	RetroMTA-OrthoMTA II	OrthoMTA(Mineral Trioxide Aggregate)
Physical Properties	-Setting time: 2m 30s -Solubility: 1.4% -Radiopacity: Not less than 3mm of aluminum	- Setting time: 5h 30m - Solubility: 3 % - Radiopacity: Not less than 3mm of aluminum - Flow: Not less than 20 ㎜ - Working time: Less than 30min - Film thickness: 27 ㎛ - Dimensional change following setting : 0.08%

9. Conclusion:

Based on the testing results, BioMTA concludes that the RetroMTA-OrthoMTA II is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

BioMTA
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E Chapman Avenue, Suite 110
Fullerton, CA 92833

Re: K132825
Trade/Device Name: RetroMTA-OrthoMTA II
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: February 25, 2014
Received: March 4, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132825

Device Name
RetroMTA-OrthoMTA II

Indications for Use *(Describe)*

The RetroMTA-OrthoMTA II is indicated for use as:
- Orthograde root canal filling material
- Repair of root perforations during root canal therapy(endodontic therapy), or as a consequence of internal and external resorption.
- Repair of root canals as an apical plug during apexification
- Root end filling
- Pulp capping

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
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